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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/373,352 08/12/99 EDGREN

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HM22/0718

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EXAMINER

CHOI, F

ART UNIT	PAPER NUMBER
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1616

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DATE MAILED: 07/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/373,352

Applicant(s)

EDGREN ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 2-9 in Paper No. 4 is acknowledged. Examiner is persuaded by applicant's argument therein, therefore, the restriction requirement set forth in Paper No. 3 is withdrawn and instead requires the following.

Claims are directed to a plurality of disclosed and/or claimed patentably distinct species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By single disclosed species, it is meant that a single disclosed species for each of the semipermeable polymer, plasticizer, peptide and surfactant; and lipophilic-attracting polymer, flux enhancer and surfactant; be elected.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with John Dhuey on 7/12/00 a provisional election was made with traverse to prosecute the invention of semipermeable polymer – cellulose acetate, plasticizer-triacetin, peptide-zein and surfactant-polyoxethylene 20 sorbitan tristearate; and lipophilic-attracting polymer-poly (ethyl cellulose), flux enhancer-hydroxypropylcellulose and surfactant-polyoxyl 40 stearate. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 4, 16, 17 are withdrawn from further consideration as

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drawn to a non-elected invention. Accordingly, Claims 1, 2, 5-15, 18-20 will be prosecuted to the extent they read on the claimed invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,5-15, 18, 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edgren et al. in view of Oshlack et al., Baichwal, and Svastano et al.

Edgren et al. teaches a dosage form having a coating composed of two layers and a exit passage (Column 3, lines 55-68, Column 4, lines 1-6). Cellulose acetate or cellulose acylate are taught as suitable polymers, triacetin as a suitable plasticizers and polyoxyethylene sorbitan tristearate and polyoxyethylene oxypropylene stearate and the like are taught as suitable surfactants (Column 4, lines 50-68, Columns 5, 6). It taught that the coat contains hydroxypropyl cellulose (Column 6, lines 59-68, Column 7, lines 1-24).

Oshlack et al. teach that zein and ethyl cellulose provide a strong, continuous film coating (Column 6, lines 43-53, Column 8, lines 63-68).

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Baichwal teach that ethyl cellulose is suitable for use in tablet having two coats (Column 10, lines 22-42).

Savastano et al. teach that polyoxyl 40 stearate is a suitable surfactant for the jacket of a tablet (Column 9, lines 8, 9).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the specific combination of claimed elements. However, the prior art amply suggests the same as it is known in the art two have two layer coatings, exit passageways, and each of the elements in combination to form the coatings. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation of formulating a dosage form that has a controlled release of medicament over a period of time.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

July 17, 2000


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

